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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,129	12/26/2001	Rajneesh Taneja	ABB1259P0072US (6762.US.0	3432

7590 11/30/2005

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,129	TANEJA ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-21 and 23-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-21 and 23-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Amendment after Non-Final Office Action, Applicant's Arguments/Remarks and the request for extension of time (3 months-granted), all filed 09/08/05 is acknowledged.

Claims 1-7, 9-21 and 23-29 are pending in this action. Claims 1, 15 and 26 have been amended. Claims 8 and 22 have been cancelled. Claims 1-7, 9-21 and 23-29 are rejected.

Response to Amendment – New Matter

In the amendment filed 09/08/05, Applicants have amended independent claims 1, 15 and 26 by incorporating the claim limitation '*an equimolar ratio*'. This amendment introduces new matter into the claims. The Examiner fails to find support in the instant specification or the originally disclosed claims for the claim limitation '*an equimolar ratio*' of *a salt* of a Group IA metal as now claimed. While it is noted that previously filed (now cancelled) claims 8 and 22 contained the limitation 'the molar ratio of said bicarbonate salt of said Group IA metal to said carbonate salt of said Group IA metal is one to one' and the specification states an 'equimolar ratio of sodium carbonate to sodium bicarbonate', support cannot be found in the specification or the originally filed claims for the claim limitation '*an equimolar ratio of a salt*'.

Additionally, the amendment to independent claims 1, 15 and 26 is an improper amendment format because the term 'bicarbonate' has been deleted, without the presence of brackets indicating deletion of the term. Furthermore, the amendment incorporating 'an equimolar ratio of *a salt* of a Group IA metal' is not proper, since there is no support in the instant specification for an equimolar ratio of '*a salt*' of a Group IA metal other than a carbonate or bicarbonate salt.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the claim recites 'an equimolar ratio of *a salt* of a Group IA metal'. It is unclear to the Examiner whether Applicant's claim recitation of 'a salt' was actually intended to be recited as ' a *bicarbonate* salt' instead.

Claim 2 is indefinite because the claim recites the limitation '*said bicarbonate salt*'. There is lack of antecedent basis for this limitation in the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7, 9-11, 15-21, 23, 24 and 26-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Phillips (US Pat. No. 6,489,346 B1) (hereafter 'Phillips I').

Phillips I ('346) discloses a method for treating acid-related gastrointestinal disorders comprising administering to a patient a non-enteric pharmaceutical composition comprising a non-enteric coated proton pump inhibitor in a pharmaceutically acceptable carrier and at least one buffering agent, wherein the pharmaceutically acceptable carrier comprises a bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal (see Abstract; Claims); (col. 11, lines 36-44); (col. 13, line 47 – col. 14, line 26). At column 13, lines 47-53, Phillips disclose that mixtures of the buffering agents can be utilized. Suitable buffering agents disclosed include sodium bicarbonate, potassium bicarbonate, aluminum hydroxide/sodium bicarbonate co-precipitate and sodium carbonate (see col. 13, line 63 – col. 14, line 14); (col. 17, lines 58-60). Potassium carbonate is disclosed at column 22, lines 7-8. Sodium bicarbonate is provided in amounts of about 1000 mg to about 1680 mg (see claim 17). The non-enteric proton pump inhibitors include a substituted benzimidazole of lansoprazole or salts thereof (see Abstract). Example IV at column 22, lines 1-39 demonstrates an effervescent formulation whereby omeprazole powder was diluted with sodium bicarbonate, citric acid and potassium carbonate to form a homogeneous mixture of omeprazole powder.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12-14, 25 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US Pat. No. 5,840,737) (hereafter 'Phillips II') in view of Phillips (US Pat. No. 6,489,346 B1) (Phillips I).

Phillips II ('737) teaches a method for treating gastric acid disorders by administering to a patient a single dose of a pharmaceutical composition including an aqueous solution/suspension of proton pump inhibitors – omeprazole, lansoprazole or other substituted benzimidazoles and derivatives thereof in a pharmaceutically acceptable carrier wherein the carrier comprises a bicarbonate salt of a Group IA metal (see abstract and claims). Phillips also teaches a pharmaceutical composition, which includes omeprazole or other substituted benzimidazoles and derivatives thereof in a pharmaceutically acceptable carrier wherein the carrier comprises a bicarbonate salt of a Group IA metal (see abstract and claims).

Phillips II teaches a method for treating gastric acid disorders wherein the Group IA metal is sodium and potassium (see claims 1-3).

It is stated that the pharmaceutical composition is prepared by mixing omeprazole or other substituted benzimidazoles and derivatives thereof with a solution including a bicarbonate salt of a Group IA metal. Preferably, omeprazole powder or granules are mixed with a sodium

bicarbonate solution to achieve a desired final omeprazole concentration (col. 7, line 50 through col. 8, line 5).

Phillip II states that the pharmaceutically acceptable carrier includes the bicarbonate salt of the Group IA metal and can be prepared by mixing the bicarbonate salt of the Group IA metal, which is preferably sodium bicarbonate, with water. The concentration of the bicarbonate salt of the Group IA metal in the composition generally ranges from approximately 5.0% to about 60%. In a preferred embodiment, the preferred salt is sodium bicarbonate and is contained in a concentration of about 8.4% (col. 8, lines 6-17).

Suitable derivatives of omeprazole can be substituted for the omeprazole or other suitable substituted benzimidazoles, wherein these derivatives include lansoprazole (col. 8, lines 41-45).

The pharmaceutical composition can be used for the treatment of gastrointestinal conditions, including, active duodenal ulcers, gastric ulcers, gastroesophageal reflux disease (GERD), severe erosive esophagitis, poorly responsive systematic GERD, and pathological hypersecretory conditions (col. 8, lines 46-61).

The examples on columns 10-19 further demonstrate various embodiments of the invention in greater detail.

Additional agents that can be added include antimicrobial preservatives, antioxidants, chelating agents and buffers (column 9, lines 23-26).

Phillips II is deficient in the sense that he does not explicitly teach the instant ratios and amounts. However, in the absence of showing the criticality of the instantly claimed ratios and/or amounts, it is deemed obvious to one of ordinary skill in the art that suitable ratios and/or amounts could be determined through the use of routine or manipulative experimentation to

obtain the best possible results, as these are indeed variable parameters within the art. Moreover, the Examiner points out that generally differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unusual/unexpected results that accrue from the instant ratios or amounts.

Regarding the 'non-enteric' proton pump inhibitor claimed by Applicant, Phillips II teaches a method for treating gastric acid disorders whereby the use of enteric coatings can be used if desired, indicating that enteric coatings are optional. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to either employ enteric coatings if drug delivery in the intestines was desired or alternatively, to exclude enteric coatings if delivery of drug to the stomach was desired. The expected result would be a drug formulation having distinct rates of release.

Phillips II ('737) does not teach a *carbonate* salt of the Group IA metal.

Phillips I ('346) teaches a method for treating acid-related gastrointestinal disorders comprising administering to a patient a non-enteric pharmaceutical composition comprising a non-enteric coated proton pump inhibitor in a pharmaceutically acceptable carrier and at least one buffering agent, wherein the pharmaceutically acceptable carrier comprises a bicarbonate salt of a Group IA metal and a *carbonate salt of a Group IA metal,* whereby suitable buffering

agents include sodium carbonate, for example (see Abstract; Claims); (col. 11, lines 36-44); (col. 13, line 47 – col. 14, line 26).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the carbonate salt of the Group IA metal of Phillips I ('346) within the teachings of Phillips II ('737) who teaches bicarbonate salts of the Group IA metal because Phillips I explicitly teaches a proton pump inhibitor formulation comprising suitable buffering agents of both carbonates and bicarbonates of Group IA metals and teaches that the buffering agents (*i.e.*, carbonates/bicarbonates) function to substantially prevent or inhibit acid degradation of the proton pump inhibitor by elevating pH of the stomach sufficiently to achieve adequate bioavailability of the drug to effect therapeutic action. The expected result would be a non-enteric coated formulation wherein the bioavailability of the proton pump inhibitor is preserved to provide for the effective treatment and/or prevention of gastric acid related disorders.

Response to Arguments

Applicant's arguments filed 09/08/05 have been fully considered but were not found persuasive.

Firstly, Applicant argued regarding the 35 U.S.C. 102(e) rejection of claims 1-7, 9-11, 15-21, 23, 24 and 26-28 over Phillips I ('346) stating, "Phillips I discloses a composition comprising a non-enteric coated proton pump inhibitor and at least one buffering agent. While Phillips I does broadly state that mixtures of buffering agents can be used, there is no disclosure

of any specific mixtures. Phillips I does not disclose an equimolar ratio of a carbonate salt and a bicarbonate salt as is presently claimed."

These arguments have been thoroughly considered but were not found to be persuasive.

The prior art (Phillips I or '346) discloses compositions and methods for treating gastric acid disorders by the administration of a pharmaceutical composition comprising non-enterically coated proton pump inhibitors (i.e., omeprazole, lansoprazole, other substituted benzimidazoles) and derivatives thereof in a pharmaceutically acceptable carrier wherein the carrier comprises bicarbonate salts and carbonate salts of a Group IA metal (see abstract and col. 13, line 47 – col. 14, line 26). The pharmaceutical composition can be used for the treatment of gastrointestinal conditions, including gastroesophageal reflux disease (GERD). As admitted by Applicant, mixtures of buffering agents are disclosed. Applicant's argument that 'no specific mixtures are disclosed' is not persuasive since suitable and preferred buffering agents include bicarbonates, such as sodium bicarbonate as well as carbonates, such as sodium carbonate (see col. 13, line 65 and col. 14, line 5). The mere disclosure of the desire to incorporate mixtures of these buffering agents, as taught by the prior art, would clearly provide for sufficient specification, the particular carbonates and bicarbonates of the Group IA metal as claimed by Applicant. The prior art discloses the same composition comprising a combination of the same active ingredients, used for the same field of endeavor and to treat the same problems as that desired by Applicant. Thus, the reference of Phillips I '346 anticipates the claims. Applicant's argument that 'Phillips I does not disclose an equimolar ratio of a carbonate salt and a bicarbonate salt as is presently claimed' is not persuasive since there is lack of support in the specification for the limitation 'an equimolar ratio' as now claimed.

Secondly, Applicant argued with respect to the Section 103(a) rejection stating, "Neither Phillips I ('346) nor Phillips II recognizes the problem addressed by the present invention. High doses of sodium bicarbonate produce large amounts of CO_2 and lead to belching which in patients with GERD can worsen their condition. Furthermore, bicarbonates having lower acid-neutralizing capacity than carbonates permitting the use of lesser amounts of buffer and the formation of smaller pills or tablets."

Applicant's arguments have been considered, but were not found persuasive. The prior art clearly teaches a composition comprising carbonates/bicarbonates useful for treating conditions of GERD, as also similarly desired by Applicant. Moreover, it is deemed obvious to one of ordinary skill in the art to determine suitable and effective doses of sodium bicarbonate, which do not cause detrimental side effects to the patient, through the use of routine experimentation to obtain the best possible results. The prior art teaches a proton pump inhibiting formulation comprising the use of the same ingredients for the effective treatment of gastric acid related disorders. Applicant has not demonstrated any surprising and/or unexpected results, which accrue from the instant formulation, since the prior art initially teaches a composition, composed of carbonates and bicarbonates salts of a Group IA metal, wherein the composition is directed particularly for the treatment of gastroesophageal diseases. Thus, it is the position of the Examiner, that given the explicit teachings of the prior art, the instant invention, when taken as a whole, would have been *prima facie* obviousness to one of ordinary skill in the art at the time the invention was made.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh

Patent Examiner

Art Unit 1615

November 28, 2005

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SUPERVISORY PATENT EXAMINER
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